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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/523,908	01/28/2005	Armin Breitenbach	6102-000075/US	9463

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EXAMINER	
AHMED, HASAN SYED	
ART UNIT	PAPER NUMBER
1615	
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/523,908	BREITENBACH ET AL.	
	Examiner	Art Unit	
	HASAN S. AHMED	1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *13 May 2010*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *28-36,38-41,45-48 and 52-56* is/are pending in the application.

4a) Of the above claim(s) *38-40,45-48 and 52-56* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *28-36 and 41* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *5/13/10,3/31/10*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

- Receipt is acknowledged of applicants' amendment, response, and IDS, all filed on 13 May 2010.
- The provisional obviousness-type double patenting rejection over copending Application No. 11/239,772 is withdrawn in view of the abandonment of that application on 22 July 2009.
- Applicants' arguments regarding the copending provisional obviousness-type double patenting rejections over Application Nos. 10/139,894; 10/140,096; 10/139,864; and 11/239,701 are persuasive. As such, said rejections are hereby withdrawn.

* * * * *

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

1. Claims 28-32, 34-36, and 41 remain rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 5,658975 ("Ulman") in view of U.S. Patent No. 6,620,429 ("Müller").

Ulman teaches a hot-melt pressure sensitive adhesive composition comprising:

- the transdermal therapeutic system of instant claim 28 (*see* col. 7, lines 9-36);

- the drug containing adhesive matrix of instant claim 28 (*see* col. 7, lines 16-17);
- the hot-meltable adhesive of instant claim 28 (*see* col. 2, lines 18-30);
- the softener (wax) of instant claim 28 (*see* col. 2, line 26);
- the drug dispersed in adhesive of instant claim 29 (*see* col. 7, lines 16-17);
- the amine-resistant silicone (polydimethyl siloxane) adhesive of instant claims 31 and 41 (*see* col. 4, line 5);
- the softener (wax) of instant claims 31 and 41 (*see* col. 2, line 26);
- the organic wax (siloxylated polyether wax) of instant claim 32 (*see* col. 2, line 26);

While Ulman does not explicitly teach all concentrations of drug recited in instant Claims 34-36, it would have been obvious to one of ordinary skill in the art at the time the invention was made to determine suitable percentages through routine or manipulative experimentation to obtain the best possible results, as these are variable parameters attainable within the art.

Moreover, generally, differences in concentration will not support the patentability of subject matter encompassed by the prior art unless there is evidence indicating such concentration is critical. "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." *In re Aller*, 220 F.2d 454, 456; 105 USPQ 233, 235 (CCPA 1955). Applicants have not demonstrated any unexpected or unusual results, which accrue

from the instant percentage ranges. The silicone resin is added in an amount of up to 70% (see col. 3, line 44) and the softener is added in an amount of up to 20% (see col. 2, line 25), reading on instant claim 41. Ulman clearly teaches use of the disclosed hot-melt composition for transdermal drug delivery (*see* col. 7, lines 9-36). The concentration ranges recited in instant claims 34-36 are broad and would be obvious for a transdermal formulation. Further, Müller teaches a rotigotine concentration of about 20% (see Example 2), overlapping with the concentration ranges recited in claims 34-36.

The Ulman reference does not address the viscosity of instant claim 18. The Ulman composition, like the instantly claimed composition, is comprised of a drug-containing adhesive matrix and a softener (*see* above). Properties are the same when the structure and composition are the same. Thus, burden shifts to applicant to show unexpected results, by declaration or otherwise. *In re Fitzgerald*, 205 USPQ 594. In the alternative, the claimed properties would have been present once the composition was employed in its intended use. *In re Best*, 195 USPQ 433.

The processes disclosed in claims 28 and 30 are not essential to a determination of patentability of the composition disclosed in the claim. The patentability of product-by-process claims is based on the product itself. "[E]ven though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product

was made by a different process." In re Thorpe, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed. Cir. 1985).

Ulman explains that a transdermal therapeutic system in the form of a hot-melt adhesive and a softener is beneficial because, "...the amount of drug released can be increased or controlled." *See* col. 1, line 67 - col. 2, line 1.

Ulman differs from the instant application in that it does not disclose the rotigotine in base form of instant claims 28 and 37. Use of rotigotine ((-)-5, 6, 7, 8,- tetrahydro-6-[propyl[2-(2-thienyl)-ethyl]amino]-1-naphthol hydrochloride) in a transdermal formulation was known in the art at the time the instant application was filed as disclosed by Müller (*see* examples 1 and 2). The rotigotine in the form of a base is formed when the rotigotine of Müller's examples 1 and 2 is mixed with sodium metasilicate (*see* col. 3, lines 38-44).

It would have been obvious to a person of ordinary skill in the art at the time the invention was made to disclose a transdermal therapeutic system comprising a rotigotine-containing adhesive matrix and a softener, as taught by Ulman in view of Müller. One of ordinary skill in the art at the time the invention was made would have been motivated to make such a composition because the amount of drug released from the transdermal formulation can be increased or controlled, as explained by Ulman.

*

2. Claims 28 and 33 remain rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 5,658975 ("Ulman") in view of U.S. Patent No. 6,620,429 ("Müller"), further in view of U.S. Patent No. RE 36,754 ("Noel").

Ulman teaches a hot-melt pressure sensitive adhesive composition (*see* above). Müller teaches a transdermal formulation comprising rotigotine (*see* above). Ulman and Müller differ from the instant application in that they do not disclose the ceresine or ozokerite of instant claim 33, however, use of ceresine and ozokerite in hot-melt silicone-based transdermal therapeutic systems was known in the art at the time the instant application was filed, as disclosed by Noel (*see* abstract and col. 5, line 1).

Noel explains that waxes such as ceresine and ozokerite function, "...to decrease the dynamic viscosity of the hot-melt pressure sensitive adhesive at temperatures equal to or below about 200°C." *See* col. 5, lines 12-14.

It would have been obvious to a person of ordinary skill in the art at the time the invention was made to disclose a transdermal therapeutic system comprising a rotigotine-containing adhesive matrix and ceresine or ozokerite, as taught by Ulman in view of Müller further in view of Noel. One of ordinary skill in the art at the time the invention was made would have been motivated to use ceresine or ozokerite in a transdermal therapeutic system because such waxes decrease dynamic viscosity of hot-melt pressure sensitive adhesives a temperatures equal to or below about 200°C, as explained by Ulman.

* * * * *

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct

from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 28-36 and 41 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-23 of copending Application No. 10/630,633 ('633). Although the conflicting claims are not identical, they are not patentably distinct from each other because '633 claims a transdermal therapeutic system made up of a hot-meltable adhesive comprising Rotigotine (*see* claim 1) and at least one softener (*see* claim 3).

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

* * * * *

Response to Arguments

Applicants' arguments filed on 13 May 2010 have been fully considered but they are not persuasive.

35 USC 103

Applicants argue that Muller describes a solvent-based TTS which is manufactured under different conditions than that claimed instantly. See remarks, pages 9-10.

Applicants are claiming the limitation of "metering rotigotine free-base into a solvent free melt" in claims 28 and 30 as a process limitation in a product claim. As indicated in the substantive rejection, the patentability of product-by-process claims is based on the product itself. "[E]ven though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process." In re Thorpe, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed. Cir. 1985).

Applicants argue that Ulman and Müller are incompatible because Ulman is designed for improved performance with hydrophilic drugs while Müller teaches a lipophilic drug. See remarks, pages 10-11.

As indicated previously, examiner respectfully submits that nowhere in the reference is it stated that only hydrophilic drugs can be employed in the disclosed composition, or that lipophilic drugs cannot be used in the composition. The section of the reference which describes delivery of active agents (see col. 7, lines 9-36) repeatedly recites delivery of a generic "bioactive agent" without any qualifier, such as

"hydrophilic bioactive agent." Thus, while the Ulman composition does teach certain advantages when using hydrophilic drugs, the reference does not implicitly or explicitly suggest that hydrophilic drugs are used with the disclosed composition exclusively.

Applicants have not shown that the composition disclosed by Ulman will be ineffective for its intended use with rotigotine free-base. When the PTO shows a sound basis for believing that the products of the applicant and the prior art are the same, the applicant has the burden of showing that they are not. In re Spada, 911 F.2d 705, 709; 15 USPQ 2d 1655, 1658 (Fed. Cir. 1990), *see* MPEP 2112.01.

Applicants argue that chemical compatibility between the polymer matrix and the drug is a basic criterion. See remarks, page 11.

Examiner respectfully submits that claim 28 recites a generic "hot-meltable adhesive". Muller teaches compositions comprising rotigotine free-base in a silicone adhesive composition (see example 1) and in acrylic adhesive compositions (see examples 2 and 3).

Applicants argue that drug concentration is a critical factor in a TTS system. See remarks, page 11.

As indicated in the substantive rejection, Müller teaches a rotigotine concentration of about 20% (see Example 2), overlapping with the concentration ranges recited in claims 34-36.

Applicants argue that "there is no guidance provided to make a solvent-free, hot-melt TTS comprising rotigotine free-base, as recited in Claim 1." See remarks, page 12.

As indicated above, applicants are claiming the limitation of "metering rotigotine free-base into a solvent free melt" in claims 28 and 30 as a process limitation in a product claim. As indicated in the substantive rejection, the patentability of product-by-process claims is based on the product itself. "[E]ven though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process." In re Thorpe, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed. Cir. 1985).

Applicants argue that Noel does not teach various properties of the claimed composition. See remarks, page 14.

The difference in objectives does not defeat the case for obviousness because, as MPEP § 2144 states, the "reason or motivation to modify the reference may often suggest what the inventor has done, but for a different purpose or to solve a different problem. It is not necessary that the prior art suggest the combination to achieve the same advantage or result discovered by applicant. In re Linter, 458 F.2d 1013, 173 USPQ 560 (CCPA 1972) ...; In re Dillon, 919 F.2d 688, 16 USPQ2d 1897 (Fed. Cir. 1990), cert. denied, 500 U.S. 904 (1991) ... ."

Noel was invoked for the teaching that use of ceresine and ozokerite in hot-melt silicone-based transdermal therapeutic systems was known in the art at the time the instant application was filed. It is noted that ceresine and ozokerite are not recited in

independent claim 28 and the limitation "softener" has been cancelled from independent claim 28.

* * * * *

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

☆

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to HASAN S. AHMED whose telephone number is (571)272-4792. The examiner can normally be reached on 9am - 5:30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Robert A. Wax can be reached on (571)272-0623. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/H. S. A./
Examiner, Art Unit 1615

/Humera N. Sheikh/
Primary Examiner, Art Unit 1615